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Robert M. Sayre, Ph.D.

June 18, 1999

Dockets Management Branch
Food and rug Administration, rm 1-23
12420 Parklawn Dr.
Rockville, MD 20857

Sirs:

Accompanying this letter are four copies of a Citizen's Petition to further define the Solar Simulator used for sunscreen testing described in 21CFR Part 352 Sunscreen Drug Products For Over The Counter Human Use, Subpart D-Testing Procedures §352.17 Light Source (solar Simulator). The petition is accompanied with four appendices providing information and supporting data.

Thank you.

Robert M. Sayre

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CITIZEN PETITION

The undersigned submits this petition under 21 CFR §10.25 and §10.30. This petition requests the Commissioner of Food and Drugs to amend, 21 CFR Part 352 Sunscreen Drug Products For Over-The-Counter Human Use; Subpart D-Testing Procedures, §352.71 Light Source (solar simulator).

A. Action Requested

The petitioner requests the Commissioner to amend 21 CFR Part 352, Subpart D-Testing Procedures, 352.71 Light Source (solar simulator). The exact wording of the existing regulation as found in the Federal Register / Vol. 64, No. 98 / Friday, May 21, 1999 / Rules and Regulations, page 27690, reads as follows:

¡352.71 Light source (solar simulator).

A solar simulator used for determining the SPF of a sunscreen drug product should be filtered so that it provides a continuous emission spectrum from 290 to 400 nanometers similar to sunlight at sea level from the sun at a zenith angle of 10 °; it has less than 1 percent of its total energy output contributed by nonsolar wavelengths shorter than 290 nanometers; and it has not more than 5 percent of its total energy output contributed by wavelengths longer than 400 nanometers. In addition, a solar simulator should have no significant time-related fluctuations in radiation emissions after an appropriate warmup time, and it should have good beam uniformity (within 10 percent) in the exposure plane. To ensure that the solar simulator delivers the appropriate spectrum of UV radiation, it must be measured periodically with an accurately-calibrated spectroradiometer system or equivalent instrument.

The petitioner hereby requests the Commissioner to consider the following proposed amended version of 21 CFR Part 352, Subpart D-Testing Procedures, §352.71 Light Source (solar simulator). Insert the sentence below into existing wording, after the first sentence which ends with; ".....wavelengths longer than 400 nanometers,":

> Solar simulators which comply with the COLIPA standard for Solar Simulators are deemed to meet the requirements for solar simulator spectral emission.

§352.71 Light Source (solar simulator).

A solar simulator used for determining the SPF of a sunscreen drug product should be filtered so that it provides a continuous emission spectrum from 290 to 400 nanometers similar to sunlight at sea level at a zenith angle of 10°; it has less than 1 percent of it's total energy output contributed by nonsolar wavelengths shorter than 290 nanometers; and it has not more than 5 percent of its total energy output contributed by wavelengths longer than 400 nanometers. Solar simulators which comply with the COLIPA Standard for Solar Simulators are deemed to meet the requirements for solar simulator spectral emission. In addition, a solar simulator should have no significant time-related fluctuations in radiation emissions after an appropriate warm-up time, and it should have good beam uniformity (within 10 percent) in the exposure plane. To ensure that the solar simulator delivers the appropriate spectrum of UV radiation, it must be measured periodically with an accurately calibrated spectroradiometer system or equivalent instrument.

B. Statement of grounds

This petition specifically seeks the adoption of the COLIPA Standard for solar simulators used in sunscreen testing and recognition that numerous solar simulators in North America and Europe appear to meet the requisite standard.

In 21 CFR Part 352, Subpart D-Testing Procedures, 352.71 Light Source (solar simulator), the agency describes the spectrum for a solar simulator to be similar to the sun at zenith angle of 10°. However, the agency does not provide the requisite solar zenith angle of 10° spectrum and does not define statistically what "*similar to*" means. A review of published standards indicates that a standard solar spectrum of this specific, zenith angle of 10°, description has not been developed.

COLIPA-Solar Simulator Standard:

COLIPA, The European Association of Cosmetic, Toiletry and Perfumery Association proposed and adopted a Sun Protection Factor Test Method in 1994. In Appendix IV pp. 16-23 of the COLIPA Sun Protection Factor Test Method ref 94/289, COLIPA adopted a standard sun and defined spectral measurement procedures and spectral irradiance limits for solar simulator compliance. A copy of the COLIPA Sun Protection Factor Test Method ref 94/289, Appendix IV pp. 16-23, is attached to this petition (see: Appendix 1).

To determine compliance to the COLIPA standard , a solar simulator is measured using a spectroradiometer with a 1 nm band pass, at either 1 or 2 nm increments from at least 250 nm to 400 nm. The measured spectra-irradiance is then multiplied by the CIE erythemal efficiency spectrum (commonly called the McKinlay-Diffey Erythemal Action Spectrum). Spectral regions of resulting effectiveness spectrum are then compared to the total risk, the COLIPA Standard requires comparison of 6 wavelength intervals. The first is solar simulator effectiveness at wavelengths shorter than 290 nm and requires that less than 1% of the total effectiveness be at these short wavelengths. This corresponds to the FDA specification that not more than 1% be shorter than 290 nm. The remaining 5 check bands range from (2) 290 to 310 nm, (3) 290 to 320 nm, (4) 290 to 330 nm (5) 290 to 340 nm, and (6) 290 to 350 nm. The COLIPA Standard allows as much as 6.2% of the effectiveness to be at wavelengths longer than 350 nm but requires only 1%. The FDA limitation that no more than 5% of the emission be at wavelengths longer than 400 nm can be determined by measuring the solar simulator emission through the visible and into the near infra red and including the analysis as part of the solar simulator measurement report. Within the COLIPA standard, the two most critical requisite points required in 21 CFR 352.17 are met: the short wavelength (<290 nm) restrictions and the similarity to a 10° zenith angle solar spectrum as detailed in the following section.

Solar Spectra Meet COLIPA Solar Simulator Standard:

A number of standard solar spectra have been adopted by national and international groups interested in testing of sunscreen products and for other purposes. A number of these have been collected and tested to determine possible compliance to the COLIPA Solar Simulator Standard. These include: CIE Air Mass 1 (0° zenith angle) (passes), CIE Air Mass 1.5 (42° zenith angle)(fails), DIN 67501 (0° zenith angle)(passes), AS 4399 (17.1° zenith angle)(passes) and the COLIPA (Composite ~37.5° zenith angle)(passes). The CIE Air Mass 1 (0° zenith angle) and AS 4399 (17.1° zenith angle) both meet the COLIPA Standard for Solar Simulators and bracket the 10° zenith angle solar spectrum adopted in **21 CFR 352.17**. It is anticipated that the specific 10° zenith angle solar spectrum will also meet the COLIPA Solar Simulator Standard. Therefore it is urged that the COLIPA Solar Simulator Standard be formally adopted. The spectra and the COLIPA Compliance Tables are provided in Appendix 2.

Rapid Precision Testing Laboratories:

Rapid Precision Testing Laboratories is a small business specializing in the measurement of sources used in clinical cosmetic and drug testing. Rapid Precision Testing Laboratories has been providing on site measurements since 1991. Measuring systems used in clinical testing at the test site may be important as optical systems can be altered during shipment. Reproducible spectroradiometric measurements in the field require additional care and the use of equipment specifically designed for transportation and field use.

Since the introduction of the COLIPA Standard for Solar Simulators, Rapid Precision Testing Laboratories has been making the requisite measurements and providing certification that solar simulators meet this standard. Within the past 15 months Rapid

Precision Testing Laboratories has measured solar simulators in more than 30 testing laboratories in North America (United States and Canada) and in Europe (France, Germany, Italy and the United Kingdom). In fact part of the data in this submission was obtained as part of a COLIPA sanctioned round-robin assessment of European SPF testing labs.

Our measurement procedures are procedurally straightforward: (1) spectroradiometer preparation and calibration, (2) check out of the system on site and measurement of the solar simulators, (3), check out and recalibration of the spectroradiometer system upon return to home laboratory.

The spectroradiometer used is an Optronic Laboratories model OL-754 with slit widths (0.25 mm, 0.5 mm, and 0.25 nm) selected to provide approximately a 1 nm spectral resolution. A 6-inch integrating sphere is currently used with a 6-mm entrance aperture. Prior to this year, a 4-inch integrating sphere had been used with a 6-mm entrance aperture. The slits selected have not been modified for several years. The wavelength is checked using a small plug in fluorescent source and agreement is obtained to within less than 0.2 nm of the desired 404.7 nm wavelength. The wavelength reproducibility of the spectroradiometer is less than 0.2 nm and this appears to be routinely achievable. The other check performed prior to measurement is the photometer response using a small quartz halogen plug in source. This is generally within less than 2% of the response at calibration. The monograph requires measurement erythemic radiation in the short UVB and UVC wavelength regions. The fact that the McKinlay-Diffey erythemic response spectrum extends over a range of 5 orders of magnitude requires that the spectroradiometer have a dynamic range of at least six orders of magnitude. The OL-754 spectroradiometer has a dynamic range exceeding that theoretically required.

Attached are data files obtained from measurements of solar simulators in 16 laboratories providing commercial sunscreen tests obtained during the past fifteen months (see: Appendix 3). At least 10 different models of solar simulators are included in Appendix 3 (Solar Light: 3 or 4 different models of single port and 3 models of multiport solar simulators, Oriel: a large area 1000 W solar simulator, Spectral Energy: a large area 1000 W solar simulator and a Dr. Mueller: 9 liquid light guide Solar Test system.) have been measured from perhaps four manufacturers and certified as meeting the COLIPA Standard and additional requirements imposed by **§351.17.** For brevity, only one representative solar simulator is shown from each laboratory even though most laboratories operate multiple COLIPA compliant solar simulators

Information possibly unfavorable to this petition:

In compiling the data on individual solar simulators which both comply with the COLIPA Standard and meet the 5% limit for visible and near infrared, there are a surprising number of solar simulators which meet COLIPA but cannot meet the 5% visible and near infrared limit. This number may represent as many as 40% of all solar simulators in testing laboratories. These solar simulators can be summarized as belonging to distinct classes: all solar simulators which use only dichroic mirrors to control visible

and near infrared, all solar simulators which use a UG-5 filter instead of the UG-11 filter. Some unique systems like a modified mercury metal halide Dr. Hönle filtered with a variable angle band pass filter. A low intensity fluorescent system with minimal visible and near infrared emission. The current specification basically requires the solar simulator to use compact arcs but not potted arcs. The current proposal appears to prevent the use of any source but those employing compact xenon arcs. The public might be better served by requiring solar simulators not to exceed a specific total power, e.g. 125 mW/cm^2. I know of no photobiological reason why visible and NIR are excluded so rigorously in the lab but cannot be in sunlight.

The author of this petition has for some time critically examined standards for solar simulator systems. Regarding the COLIPA standard for solar simulators, the author has been critical in the past of the acceptance limits adopted in the standard. Particularly, the author has suggested that the standard solar simulator has relatively too much short UVB radiation and too little long wavelength UVA. The author has felt that the limits adopted are not particularly well chosen. (see appendix 4 for appropriate abstracts addressing this issue submitted to scientific meetings). However, the solar simulator specification adopted in **21 CFR 352.17** regarding the amount of visible and near infrared radiation allowable in the system precludes simple filter changes. Additionally the author feels that substantially changing the acceptance limits would negate all the testing which has occurred since the issuance of the tentative final sunscreen monograph in 1993. It might also jeopardize testing which has been on going in support of IND and NDA investigations submitted or in preparation for submission to the FDA.

C. Environmental impact

The agency has established categorical exclusion under §§ 25.31 (see: 21 CFR Parts 310, 352, 700 and 740 Sunscreen Drug Products For Over-The-Counter Human Use; Final Monograph, Supplementary Information IX. Environmental Impact, Federal Register / Vol. 64, No. 98 / Friday, May 21, 1999 / Rules and Regulations, page 27686) that action of this type, does not individually or cumulatively have significant effect on the human environment and therefore neither an environmental assessment nor an environmental impact statement is required.

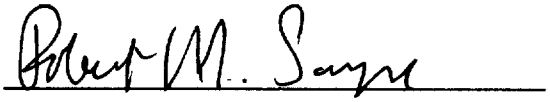
D. Economic impact

The petitioner understands that an assessment of economic impact is required to be submitted only when requested by the Commissioner following review of the petition. However, it is the opinion of the petitioner that, since most laboratories operating solar simulators already conform to the COLIPA standard, the requested action will have no effect on: (1) Cost (and price) increases to industry, government, and consumers; (2) productivity of wage earners, businesses, or government; (3) competition; (4) supplies of important materials, products, or services; (5) employment; and (6) energy supply or demand, beyond that already detailed in 21 CFR Parts 310, 352, 700 and 740 Sunscreen Drug Products For Over-The-Counter Human Use; Final Monograph, Supplementary Information VII. Analysis of Impacts, Federal Register / Vol. 64, No. 98 /

Friday, May 21, 1999 / Rules and Regulations, page 27683. There will be an impact should the COLIPA Standard for Solar Simulators not be adopted. Such failure will cause laboratories to maintain two different solar simulators for sunscreen testing required by both the FDA and Europe. More importantly it will increase the cost to international manufacturers of suncare products by causing two different sets of efficacy tests to be performed.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

(Signature) 

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